Chapter 2

Key Aspects for Implementing ISO/IEC 17025 Quality Management Systems at Materials Science Laboratories

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Abstract

Implementing a quality management system based on the requirements specified in ISO/IEC 17025 standard at materials science laboratories is challenging, mainly due to two main factors: (i) the high technical complexity degree of some tests used for materials characterization and (ii) the fact that most materials science laboratories provide materials characterization tests and also carry out research and development activities. In this context, this chapter presents key subjects while implementing a quality management system at materials science laboratories and some considerations on strategies for effectively implementing such systems.

Keywords: quality management, quality assurance, materials metrology, ISO/IEC 17025, materials science laboratories

1. Introduction

The constant strive for innovation on the development of new products and services led, in the last decades, to a growing interaction between research and development (R&D) laboratories. Most of these laboratories are from universities and research institutes and interact with diverse branches of productive sector. As a consequence, several of them opted for implementing a quality management system based on an international requirement standard aiming at improving products and services reliability [1–6].

Particularly interesting cases are the materials science laboratories [7]. Many of these laboratories, originally headed almost exclusively to R&D activities, became interested in providing accredited tests for materials characterization. As a consequence, they should adopt a quality management system based on the ISO/IEC 17025 requirements standard [8]. On the other hand, materials characterization laboratories specialized in providing accredited high-technology tests are constantly pushed to carry out R&D, in order to improve or develop new processes and services. One way or another, both cases describe scenarios where quality management system must run in an environment where R&D and accredited testing services co-exist.

Considering this context, implementing quality management systems at materials science laboratories is a challenging task due to several reasons. The first point is the fact that whilst the implementation of an ISO/IEC 17025 oriented quality management system at testing laboratories is a consensus, the advantages and disadvantages of applying quality management concepts to R&D activities are still issues widely discussed by the quality management community. Indeed, the main aspects of this controversy are highlighted in the articles of Mathur-De-Vré [9] and Krapp [10]. They state that adding quality management concepts, like metrological traceability, trackability and rational human resources management, must not restrain the flexibility necessary in order to carry out R&D activities.

In spite of this contradiction, materials science laboratories, but also R&D laboratories of several scientific areas, start to see the standardization promoted by the implementation of a quality management system based on ISO/IEC 17025 standard as a way to reduce costs, reduce tests execution deadlines, satisfy customers and especially add quality to their services and products. More recently, an article published in *Nature* has drawn attention to how quality management and quality assurance concepts could improve R&D activities and results [11].

In this context, this chapter aims to discuss practical aspects for implementing a functional quality management system at materials science laboratories. Considering this approach, in the reminder of this section a brief discussion on the basic principles of ISO/IEC 17025 will be presented, followed by a practical approach related to the main aspects of quality management system implementation.

The aspects discussed in the aforementioned method are mainly associated with the experience of the authors regarding the implementation of an ISO/IEC 17025 oriented quality management system at the Materials Metrology Division (Dimat) of the National Institute of Metrology, Quality and Technology (Inmetro), the Brazilian National Metrology Institute (NMI).

1.1. ISO/IEC 17025—General requirements for the competence of testing and calibration laboratories standard: basic principles

ISO/IEC 17025 specifies the basic requirements for the competence verification of laboratories carrying out testing and calibration activities, focused in meeting customer expectations and keeping organized laboratory records and documents. These requirements relate to most, if not to all, the laboratory activities concerning testing and calibration services provided by the laboratory, from the control of documents and records to the technical procedures standardization. The standard separates these requirements into two wide classes: management

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requirements and technical requirements. The former will be briefly described in this section, since complete information can be found in the ISO/IEC 17025.

Management requirements are mainly related to organization, control and update of documents, analysis of contracts and monitoring optimization of the quality management system. Its main topics are summarized as follows:

- Management: this item includes primarily a definition of the company/laboratory organization, describing the quality management and technical team, the attribution of responsibilities and the clear commitment to the quality management principles;
- Control of documents and records: this section incorporates the design of a system to control the revision of documents and ensure access to up-to-date documents, avoiding use of obsolete versions. It also encompasses a system to records control;
- Review of requests and contracts: review of tenders, requests and contracts must cover all the contracts with clients and with suppliers and subcontracted service providers, in as much as these are related to the activities covered by the quality management system;
- Non-conforming control: it includes identification of the non-conforming cause, its corrections, the application of further corrective actions when necessary and prevention of potential non-conformities. It also includes long-term monitoring of corrective actions effectiveness;
- Contact with the client: this point counts all the contacts with clients. It comprises on clients' complaints;
- Monitoring and optimization of quality management system: this item covers several actions, like a programme that monitors and collects information on the effectiveness of the quality management system. It equally encapsulates critical analysis of such information in order enhance the system's optimization.

On the other hand, technical requirements are directly related to testing and calibration procedures, as summarized below:

- Technical staff: covers mainly the evidence of technical staff qualification with respect to the assigned tasks;
- Control of environmental conditions and accommodations: covers adequacy of accommodations, including its organization, to activities carried out at the laboratories. Furthermore, if testing or calibration activities demand specific environmental conditions (temperature and humidity) such conditions must be controlled;
- Test and calibration methods: comprises all the aspects related to the methods used in the laboratory, like evidence of the use of standard methods and validation of non-standard and laboratory-developed methods. It also includes the evaluation of uncertainty of measurements;
- Equipment: contains identification and guaranties of working conditions and, when necessary, calibration of the laboratory equipment;

- Measurement traceability: deals with traceability via calibration or use of certified reference materials or standards;
- Sampling: involves the use of standard sampling methods adequate to different sort of materials;
- Handling of testing and calibration items: covers definition of procedures to identify and handle samples to tests, as well as records of trackability;
- Results quality assurance: covers a programme of actions related to the quality assurance of obtained results. Such a programme may contain actions, for example, participation in inter-laboratory comparison or proficiency-testing programmes; and
- Reporting results: this topic consists of the procedures required for communicating tests and calibration results to the clients.

Up to this date, ISO/IEC 17025 standard was last revised and confirmed by ISO in 2010 and is currently under a new revision process [12]. Accordingly to some stakeholders, several aspects should be reviewed in order to modernize the standard concepts and specifications, as, among others [13] quality system management designing based on performance and process, trackability, modernization of requirements related to software and electronic records and the evaluation of other standards (as ISO/IEC 17065—conformity assessment—requirements for bodies certifying products, processes and services, for example) relevance to ISO/IEC 17025.

Although these requirements are separated into two main classes, they should not be seen as isolated. As a matter of fact, it is easier to see the relation between them if one considers the basic system development concept underneath the implementation of a quality management system based on a requirement standard. This concept is represented in **Figure 1**.

Any quality management system such as the ISO/IEC 17025 is based on a tripod formed by policies, procedures and records.

Policies are the platform for the development of the system. They must clearly dispose the figures responsible for the different processes that constitute the management system itself, as well as the basic principles that encompass these processes. As an example, the policy for documents control may dispose that update and access control is the responsibility of a centralized system (a document control centre) for this very purpose, whilst the production of technical documents is the responsibility of the laboratory staff. Based on this simple policy, documents control centre and laboratories can, together, develop procedures to ensure the correct access, update and utilization of documents.

As per ISO-specific nomenclature, all policies must be documented. On the other hand, procedures describe how a quality management process must be done and how to register its execution. They apply to most of the processes carried out in a laboratory, stretching from technical procedures for testing and calibration to procedures about documents and records production, contracts and suppliers' evaluation, and quality assurance procedures, to name but a few.

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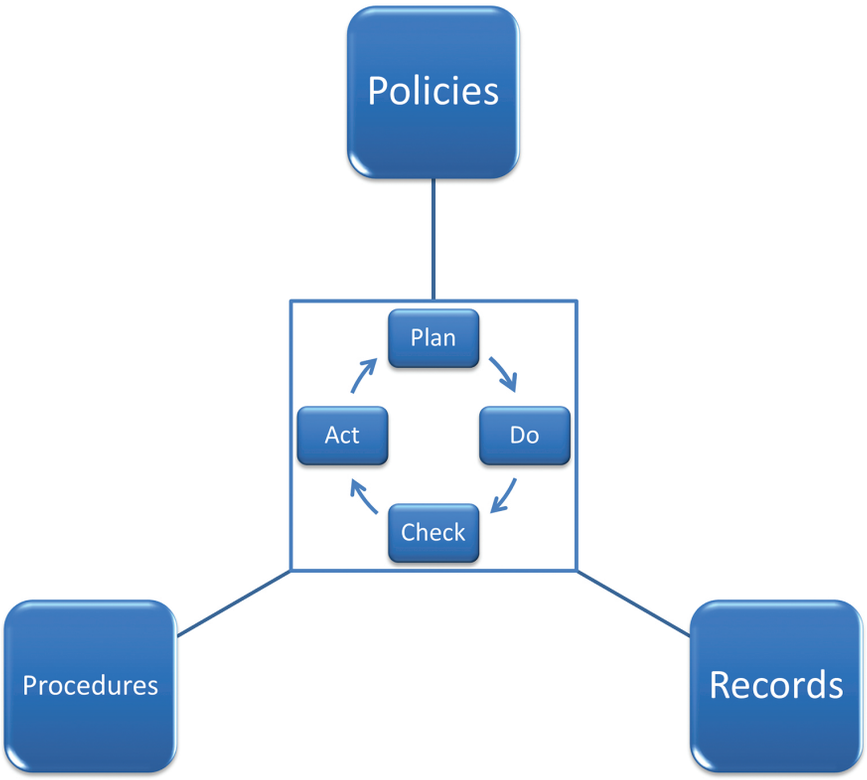

Figure 1. Basic concepts underneath a quality management system based on a requirements standard.

Finally, it is worth to mention that the records comprise not only testing and calibration results, but also complete status of laboratory equipment, staff training and ambient conditions. In other words, the records consist of all activities related to the quality management system. The way the recording is performed, stored and made available is usually specified in procedures. Thus, all requirements should be considered in unison so as to design a functional quality management system.

One last, but fundamental aspect related to the policies-procedures-records tripod is that although it constitutes the base (policies) and the tools (procedures and records) for the quality management system operation, the system itself is under constant improvement. In this way, procedures and even policies are constantly evolving in order to simply correct eventual non-conforming or to optimize the system. In **Figure 1**, this characteristic is depicted by the central cycle representing the 'plan-do-act-check' system (PDCA).

All the requirements disposed in ISO/IEC 17025 must be fulfilled when implementing the quality management system. However, the extensive discussion of each one of the requirements is not the intent of this chapter. Instead, this chapter will cover the aspects regarded as key requirements for implementing a functional and flexible quality management system at materials science laboratories. Section 3 addresses some practical topics concerning strategies for implementing a quality management system and, lastly, final considerations are presented in Section 4.

2. Key matters in quality management systems in materials science laboratories

2.1. Organization of laboratories: the quality management system set out

Implementation of a quality management system at materials science laboratories involves a clearly specified chronogram. Additionally, responsibilities of the laboratory staff members should be defined in detail in order to organize the process.

However, a critical question concerning the necessary units for work organisation whilst implementing a functional and lissom quality management system must be answered.

Most of materials science laboratories make use of several experimental techniques to characterize different materials properties, such as structure, chemical composition, and thermophysical and mechanical characteristics among others. Therefore, as the scope of techniques associated with materials science covers a wide area, it is not rare that the same organization (company or laboratory) holds multiple analysis techniques that may differ from applications, scale or sort of materials. In addition, each one of them demands very specific requirements concerning facilities and staff.

One possible approach is to gather similar experimental techniques in the specific laboratory units. The quality management team, in co-operation with the technical staff, may choose similar and/or complementary techniques to compose each unit. Another approach is to organize the laboratories driven by external demand. For example, an institute/company for testing building materials may organize multiple laboratories following the regulatory compliance, such as energy efficiency, thermal comfort and fire safety. Another common case is that of laboratories inside companies producing materials, designed for materials quality control. In such cases, the laboratories can be organized according to specific production needs.

On the other hand, not only external demands, but also internal factors should be considered. The staff size must be compatible with the experimental complexities and tests demands. Besides, physical and financial aspects are also important, because a laboratory divided into multiple locations without financial autonomy may result in an unnecessarily complicated management system that could hamper the management.

Furthermore, if the laboratory belongs to a company or may form another legal entity, the organizational structure must ensure that duties are clearly assigned, eliminating the possibility of conflict of interests between the laboratory and any other operating units.

Considering these aspects, it is the authors' view that a rational organization of technical infrastructure and equipment in a minimal, but necessary, number of different laboratories or units can minimize financial and human resources costs. If the structure is spread among many different laboratories, the production of documents may turn into a burden, resulting in a highly complex and oversized quality management system, presenting, for instance, redundant procedural documents in different laboratories. Otherwise, the distribution of the structure between few laboratories may produce a frame where many different techniques are condensed in a single unit, creating very complex laboratories which will be hard to manage.

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Besides the practical aspects presented above, it is equally important to understand how the customer sees the company's activities. As an example, consider a client who wants tests for compliance to some specific standard or regulation, as is the case of characterization of thermal conductivity for insulator materials. In this case, it will be much easier to maintain a quality system and to organize records and documents when laboratories are directly related to the sets of tests performed for each regulation. However, if the customers see the organization as a centre of excellence in materials science, organizing laboratories by similar techniques could be more appropriate.

As one can see, the approach adopted to organize the technical infrastructure in laboratories or units is a 'tailor made' task that impacts several aspects of the strategy used for implementing the quality management system. It determines the background for the definition of policies and processes common to all laboratories, such as documents control, services and supplies acquisition, customer service, internal audit, control of records and management of nonconforming works and events.

After that technical requirements specific to each laboratory/unit could be easily implemented by combining particularities of each one of them with the common policies and processes, in order to optimize system standardization. In this aspect, a well-designed organization of laboratories/units automatically shows that keeping some processes common to all laboratories minimizes the efforts from technical staff in document production and also improves the collaborative process for quality management.

2.2. Control of documents and records

The purpose of a document control system is to deal with the large amount of documents, such as procedures, reports and forms generated by the quality management system. In such a system, any given document must be considered as a unique element. It must have a unique identifier, like a name or code, and each one of these documents has a lifetime in the system, from its release to its cancel dates. The documents *per se* evolve over time, necessitating thus, a revision. Therefore, a functional documents control system must keep track documenting the corresponding characteristics.

The system must control not only the internal procedures developed within the company or laboratory, but it must also include instrument manuals, software, drawings, standards and regulations as well as external source documents (i.e. national or international standards for testing of materials). This last class of documents usually demands special attention, since the revision of such standards by the responsible organizations must be periodically monitored by the laboratory, in order to avoid the use of obsolete external standards.

In practice, the complexity of such a system depends on each case. For small laboratories carrying out a small number of tests, an electronic spread sheet could be enough for document management. However, for larger corporations with several laboratories, a system running a consolidated documents database allowing relational searches could be a proper choice. Apart from its complexity, the system must keep track of a certain number of document characteristics such as:

- release date;
- revision date (from the first to the later revision);
- unique identification for each revision (revision number); and
- copies of all revisions, authors, reviewers, and the person(s) who approved each document.

Additionally, invalid and obsolete versions of documents must be clearly identified in the system, in order to avoid misuse. Finally, the system must provide access to all its documentation to the users.

Document management goes beyond an effective document control system. The standardization and documentation of processes is a tool to make activities much more effective and efficient. Documents should be easy to read and simple to use. They must disseminate knowledge within the organization. They could be hierarchical and should be referred to each other in such a way that it improves the document writing process by reducing the amount of rework. They should be based on consensus of those involved in the process. Each document must describe the process accurately, making use of figures, tables and flowcharts as and where necessary. They must be written with its practical use in mind and focused on being easily understood.

Records must be also included in a management system. Several records must be kept at the laboratory level—such as testing results—and must be organized considering the particularities of each laboratory or unit.

There are other records that can be kept organized outside the laboratory to provide easy access, as follows:

- meeting minutes,
- management review minutes,
- implementing reports,
- item registration,
- personnel documentation and
- test item handling records.

The record management system may also keep track of measures of productivity, assisting management decisions. It is the authors' view that control of records may impose bottlenecks when a quality management system is applied to R&D activities. Indeed, during R&D projects execution, detailed investigation of a considerable number of parameters is carried out. These activities result in a large number of preliminary results that will not be included in the research outcome. However, even these preliminary results must be accounted as controlled records by the quality management system.

All these aspects make designing a system to control documents and records a customized task, which must take into account specific characteristics of the company/laboratory, as the

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mechanism to provide rapid access to documents and eventual access privileges. However, once a system of documents and records management is working properly, it makes laboratory-daily activities and follow-up tasks easier, since the information is always organized and readily available.

2.3. Customer relationship service

Customer service is a common requirement for all testing laboratories and the usual approach perfectly applies to materials science laboratories. When a company or institution structure consists of several laboratories, the usual approach can be applied. Establishing a specialized sector for customer service is a suitable policy that allows laboratories technical staff to spend more time for laboratories activities (testing services and R&D activities). Additionally, by minimizing the direct contact between the client and the technical staff, the customer service sector may also avoid or at least reduce some unpleasant situations, like external pressure for anticipating deadlines or questions about price. The customer service sector should be assigned to handle all the communication between the company and the clients, from the first commercial contact to the finalization of the contracted service. It is not uncommon that the same channel used for customer service also fulfils the function of customer's claims channel. Although these observations are pretty obvious, it is addressed here because it is crucial for R&D laboratories wishing to start providing accredited tests to properly take care of costumer services from the start.

Although customer service sector limits the direct contact between the client and the technical staff, in the case of materials science laboratories this direct contact should be done in order to clarify technical aspects related to the test as demanded by the costumer. These technical aspects normally relate to the use of specific experimental procedures and an eventual deviation from standard testing procedures in order to suit customer needs. It may also be due to some specific characteristic of the tested material. It is important to mention that when the laboratory uses methods other than standardized ones, even due to customer's request, such methods must be validated by the laboratory technical staff.

2.4. Calibration, traceability to the SI and quality assurance of test results

The most relevant impact of implementing a quality management system in any laboratory developing tests and R&D is the quality assurance of the experimental results. This assurance is important not only to a client interested in materials properties characterization, but also to the R&D activities, since traceability and reproducibility of results are deemed as key factors in science and technology. In this aspect, the implementation of a quality management system based on the ISO/IEC 17205 shall demonstrate confidence in experimental results. From a technical standpoint, the establishment of calibration and traceability to appropriate measurement standards is fundamental, and consequently the quality assurance can be demonstrated. As such, this section discusses how calibration and traceability can be handled in materials science laboratories in order to improve quality assurance of experimental results.

ISO/IEC 17025 standard requires that all equipment used for testing or calibration must be calibrated in order to assure the quality of results. This applies also to subsidiary measurements, such as environmental conditions monitoring, as long as they have a significant contribution to the total uncertainty of the results. An useful example is the International Vocabulary of Metrology (VIM) [14], at page 28, defines calibration as '… operation that, under specified conditions, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication'. The purpose of the calibration is not simply to ensure that the equipment is providing a correct result, but most of all, to guarantee a link of this measurement with the unit definitions in the international system of units (SI). This link, that establishes a relation between the result of a measurement and the abstract SI units, is called metrological traceability.

This traceability, however, can also refer to a measurement procedure including the measurement unit or a measurement standard. The concept of traceability is implied when dealing with traditional calibration procedures, such as the calibration of a scale. In this case, a standard weight is used to calibrate the scale in a simple procedure. Therefore, traceability is secured by an unbroken chain of calibrations tracing back to the international mass standard, which is unique and is the physical realization of the kilogram unit. This simple procedure, however, is far from the reality of an engineering materials testing laboratory.

When dealing with tests of materials, some of their properties may not be directly linked to the SI through a simple metrological traceability chain [15]. Typically, even a simple measurement of a material property involves many different measurements and links to several SI units to guarantee the metrological traceability. An useful example is the thermal conductivity, whose unit is [W/m K] or equivalently [m kg s^3 K], measured by the GHP method. In this case, the metrological traceability to four different units needs to be provided, which in turn, requires calibration of several instruments used in the process. Although this is the primary method to establish the traceability to SI, this is a very laborious task and, in some cases, it is hard to be used for some materials characterization techniques. In these cases, alternative approaches are used [16].

Another topic that makes testing of materials not so easy task is that some properties of a material are not intrinsic but dependent on the measurement procedure, which is called a procedural property. This means that the measurement of a given material property can return different values depending on the measurement method. A typical example is the hardness. In this case, the traceability is guaranteed by not only the calibration of the instruments but also by a documented standard defining the method. Finally, sometimes a measurement cannot be linked to SI, as a result of the measurement is not an SI unit but a classification on an appropriate numerical scale. Once again, the metrological traceability in this case is given by a measurement standard procedure and some reference materials. An example is the Mohs Hardness scale.

http://dx.doi.org/10.5772/66100

In all cases, the ISO/IEC 17025 standard gives alternatives to foster confidence in measurements by establishing the traceability to appropriate measurement standards. Those alternatives are as follows:

- the use of certified reference materials (CRM) provided by a competent supplier;
- the use of specific methods and/or consensus standards; and
- participation in suitable inter-laboratory comparisons where possible.

For materials testing, the use of certified reference materials (CRM) is typically the preferred choice. It is important that the reference material should be accompanied by a document, issued by a recognized organization. The latter provides values of specific properties with associated uncertainty and metrological traceability, using validated procedures. It is worth mentioning at this point that, when dealing with a specific material, there are many of its properties that can be assessed and used as a reference in a measurement, but the CRM is typically certified for just one of its properties of interest.

The certification of this property can be achieved through a measurement using a primary method, with the lowest uncertainty and with the necessary traceability. This reference material is then used to provide the traceability to the measurements of this property in a much simpler way. The drawback is that the measurement uncertainty is a bit higher than the one obtained by primary methods, but most of the time this is low enough for the researcher's purpose.

There are still cases where one cannot certify a reference material using a primary method. In this case, the certification is achieved by consensus. This means that different laboratories make the measurement using a given protocol, and the mean value is used as a reference value for that given property.

A laboratory participating in such a comparison can (or cannot) demonstrate their competence and measurement capability, without having to provide traceability to SI for their results. This is similar to laboratories that realize the SI units, and therefore, have no physical standard that can be used to calibrate their instrument. Those laboratories undergo international inter-laboratory comparisons with other laboratories in the same status, in order to mutually guarantee their measurement capabilities. In the specific case of national metrology institutes, there is the possibility of participation in key comparisons organized by the Bureau International de Poids et Mesures (BIPM) [17].

If there is no CRM available or, if no inter-laboratory comparisons have been performed, an alternative way to assure the quality of test and calibration is to periodically perform intra-laboratory comparisons. In an intra-laboratory test, two or more researchers perform the material measurement, using—preferentially—a CRM and calibrated equipment, and the results are compared. With this practice, it is possible to analyse data and detect trends that can influence the result and uncertainty.

At BIPM there are several consultative committees (CC) that are responsible for the base SI units, namely:

- length,
- mass,
- time,
- electric current,
- thermodynamic temperature,
- amount of substance and luminous intensity.

Indeed, the same applies for the derived units or for specific fields such as acoustics, ultrasound and ionizing radiation. There is, so far, no specific CC for materials. BIPM understands that any material property can be treated under one of the current CCs. For example, thermal conductivity is treated under the consultative committee for thermometry (CCT).

An important forum for discussion on measurement methods and procedures are the ISO technical committees (TC). Once again there is no specific TC for materials metrology, but there are so many TCs; it is unlikely that one given property of a material is not treated in one of the committees. ISO is a normative organization and as such it is concerned with publishing standards, either for a material testing or for method standardization. Typically, a normative standard is produced when there is already a well-established consensus in the validity of such a method or test that one wants to standardize. However, one can propose inside a TC a study group to develop and validate a new method before writing the standard, taking advantage of the internationality and wide extent of the members.

This procedure is however not preferable, since it may take too long to fully develop new methods, and the ISO time is short and well defined.

A solution to this problem is the pre-normative forums. One of the most important forums is the Versailles project on advanced materials and standards (VAMAS), whose main objective is to '…promote world trade by innovation and adoption of advanced materials through international collaborations that provide the technical basis for harmonization of measurement methods, leading to best practices and standards' [18]. The VAMAS has been founded under the auspices of the G7 economic summit in 1982 and includes a number of representatives from many countries in the world. The VAMAS consists of the technical working areas (TWA) dealing with a class of materials or a given property of materials, such as polymer composites, mechanical properties of thin films and nanoparticle populations. In every TWA, there are many projects that deal with specific subjects. In this way, one can propose new measurement methods or new testing for new materials, run inter-laboratory comparisons with the collaboration of different national metrology institutes and also other stakeholders from industry and academia.

The VAMAS is also liaising with the BIPM in the development of materials metrology. While VAMAS can propose new procedures and measurement methods, BIPM would run the inter-laboratory comparisons among the NMIs using their well-established system of key comparisons. Finally, if the project is successful, one might forward it to the ISO and develop a standard out of it, since it has already been tested by a worldwide community.

http://dx.doi.org/10.5772/66100

In order to manage equipment and reference materials, calibration routine and records, it is critical to have a calibration programme. In such a programme, the laboratory shall control the calibration status of the equipment and the reference materials that are relevant for the testing procedure. Different equipment presents different needs regarding its calibration periodicity. For instance, a scale or ruler can be calibrated on an annual basis, because their daily use does not change their calibration condition, if well conserved and appropriately handled. On the other side, some types of apparatus may require a calibration before the beginning of each measurement, as their calibration status may not be valid for a long period. Finally, for multi-faceted equipment used in typical material testing laboratories, their calibration is too complex to be done on a periodical basis. One must, however, confirm that performance properties or legal requirements of the measuring system are achieved. This is called verification. When possible, both calibration and verification of the equipment should be done with the use of reference standards or certified reference materials. It is also quite important to verify the status of any apparatus when it goes through maintenance or when it is used outside the laboratory's environment.

Not only equipment, but reference standards and CRM must also have a systematic control of their calibration situation or validity of its certification. While reference standards can be re-calibrated on a periodic basis just like any equipment, CRMs normally have a short life span that guarantees their properties. After its expiration, the laboratory must then acquire new CRMs or, when possible, get its re-certification. Particularly to some materials, due to their stable properties, the validity of their certification can be indefinite. As an example hereto, the alumina powder (corundum) reference material for quantitative phase analysis using the powder diffraction method is mentioned. This reference material has been developed by the NIST [19] whose certification is valid indefinitely as long as it is stored and handled according to its certificate.

Additionally, in some particular cases, it is not possible to calibrate the instrument and there is no CRM available for instrument verification. In such cases, ISO/IEC 17025 recommends to repeat the tests using samples already tested and retained in the laboratory and/or to compare the results of tests performed using different methods, in order to provide some evidence of quality assurance.

The routinely monitoring of calibrations or verifications can be recorded with the use of control charts that provide an easy way to examine the overall status of the equipment or reference standards and identify eventual trends that may affect the results of tests. In order to assure the quality of results, it is important that the laboratory defines and documents the acceptance criteria of the calibrations of equipment, reference standards, and the certificates of CRMs. The control charts are viewed as a very valuable tool for this task. It is worth mentioning at this point that activities related to quality assurance not only involve technical aspects, but also organizational elements that permeate work at all stages. Thus, a quality system with good documentation, internal and external auditing and records (equipment maintenance, corrective/preventive actions, etc.) strongly supports quality assurance.

2.5. Evaluation of uncertainty of measurements

Measurement uncertainty is a quantitative indication of quality for measurement results. When the uncertainty related to a result is not declared, this result cannot be compared with specified reference values or standards. As a matter of fact, even results from different tests related to the same material/sample are hard to compare without evaluation of uncertainty. Uncertainty evaluation is essential to guarantee the metrological traceability of measurement results and to ensure they are accurate and reliable. Additionally, measurement uncertainty must be accounted for whenever a decision has to be taken based on measurement results.

In this context, progressive globalization of markets pushed for the use of a standard procedure for evaluating uncertainty of measurements, in order to assure comparability of results and, consequently, mutual recognition in metrology. In this aspect, laboratories accredited under the ISO/IEC 17025 standard aiming to demonstrate their technical competence and the ability to properly operate their management systems are required to evaluate uncertainty of their measurement results. The two main approaches commonly used for evaluating measurement uncertainty are the bottom-up and the top-down and both of them will be briefly discussed here.

The bottom-up approach is more often used for classic physical metrology systems, such as mass or dimension measurements. It involves using a model equation (the one used for the calculation of the measurand) as a starting point and then considers all individual uncertainty contributions. This is the approach that is well described in the guide to the expression of uncertainty in measurement (GUM) [20] and it uses the law of propagation of uncertainties as its base. The GUM is a guide to uncertainty evaluation and it is the more widely accepted approach for uncertainty evaluation in metrology studies regarding the comparison of results.

Considering the approach described in GUM, the measurand is described as a function of several variables called input quantities. For each input quantity, the sources of uncertainty should be evaluated, quantified, modelled as a random variable, and then classified as being type A or type B.

Type A uncertainties are the ones evaluated by statistical methods. Sources of uncertainty evaluated using non-statistical methods such as documented values or elicited by expertise are called type B uncertainties. For example, during a simple mass measurement, the repetition and uncertainty from calibration standards are sources of uncertainty. The former is Type A uncertainty and the latter is Type B uncertainty. However, an accurate measurement could compute the buoyancy effect and new sources of uncertainty should be taken into account such as air density changes arising from temperature or pressure variation. It is worth mentioning at this point that the measurand model plays a critical role in uncertainty evaluation.

All sources of uncertainty can be communicated using an Ishikawa diagram [21], also known as the fishbone diagram. The measurand plays the role as a principal bone and each input quantity as an adjacent bone. Each input quantity should have its uncertainty sources attached to it. The fishbone diagram gives in a single chart a qualitative summary of all sources of uncertainty for a given measurement model.

http://dx.doi.org/10.5772/66100

After quantifying the sources of uncertainty, the partial derivative of the measurand model with respect to each input quantity should be calculated. The partial derivative is called sensitivity coefficient. The standard deviation of each uncertainty source multiplied by the sensitivity coefficient gives the standard uncertainty. Considering the result obtained for a given measurand as a function of *f n* independent variables. The uncertainty can be written as:

$$u^2_{f(x,\,y,\,z,\ldots,n)} = \left(\frac{\partial f}{\partial x}\right)^2 u_x^2 + \left(\frac{\partial f}{\partial y}\right)^2 u_y^2 + \left(\frac{\partial f}{\partial z}\right)^2 u_z^2 + \ldots, + \left(\frac{\partial f}{\partial n}\right)^2 u_n^2 \quad (1)$$

where u_f is the uncertainty associated with the measurand, the partial derivatives are the sensitivity coefficients and the terms ui ($i = x, y, z, \ldots, n$) are the uncertainties associated with each one of the independent variables.

The standard uncertainties could be plotted in a bar-like chart. This kind of chart is known as uncertainty budget and brings to light critical information about the measurement quality. With this chart one can easily assess the major sources of uncertainty that must be reduced in order to enhance the measurement accuracy. This last aspect points out that GUM methodology is also a management tool for continuous improvement.

In materials science measurements, the bottom-up approach is suitable for limited tests where it is possible to address the measurand via a liable model. Some cases where bottom-up approaches can be applied are the measurement of specific area by gas adsorption [22] and measurement of thermal conductivity by the guarded hot plate (GHP) method [23].

For cases where bottom-up approach does not fit or its application is much complex, the top-down approach is a suitable tool for estimating uncertainty associated with a measurand. The top-down method is a phenomenological approach that is based on the validation and the quality control tests results, assuming that these results: (i) cover all the influence factors and (ii) are representative for all measurements. In this approach, which is described in ISO 5725 [24], uncertainty will always have components evaluated from reproducibility and bias.

The top-down approach is more often used for chemical, biology and materials measurements when some relevant quantities cannot be addressed in a mathematical model. For example, the top-down method was used by De Temmerman et al. [25, 26] to evaluate the uncertainty associated with the measurement of particle size using transmission electron microscopy (TEM).

To perform the top-down approach, it is necessary to use an experimental design that addresses the method variability and a set of reference materials to estimate the bias component. This approach could be expensive and time consuming due to the large number of measurements that must be carried out in order to explore the influence of all the relevant experimental parameters on the results. One example is the use of the top-down approach to evaluate the uncertainty associated with purity analysis by using differential scanning calorimetry (DSC) [27]. Furthermore, in some cases, the applied procedure could become ineffective if future tests

must be performed under experimental conditions not contemplated in the experimental design used for uncertainty evaluation.

Besides the issues related to the use of different approaches for estimating uncertainties, measurements of material properties have some particularities that must be taken into account when evaluating their uncertainties. One of them is that these measurements are often made to give representative measurand values related to a considerable amount of material, such as a lot. In addition, in surface analysis there are some cases in which the measurement is made in a local area of a specimen instead of the material as a whole. In these cases, measured values scatter not only by reproducibility of the measurements, but also by possible non-uniformity of the material [28]. These two components are eventually merged when estimating uncertainty for a reference material. Additionally, it is worth mentioning at this point that (Section 2.4) material properties can be classified in two categories: intrinsic properties and procedural properties.

Intrinsic properties are inherent to the material and its value does not depend on the measurement procedure. On the other hand, procedural properties are totally dependent on the measurement procedure. So, in this last case, two or more property values can only be compared if the measurement procedures have been exactly the same.

3. Practical view for implementing quality management systems

3.1. Strategies for implementation and its progress monitoring

There are several ways to approach the implementation of a quality management system based on ISO/IEC 17025 in a laboratory. It is the authors' view that most of the time such a system will be implemented in a laboratory that is already in operation. Therefore, it is important that the strategy adopted for implementing the system minimizes the impact of the implementation process on the testing and R&D activities carried out by the laboratory. Furthermore, the strategy shall be flexible and prioritize constant follow-up in order to avoid repetition of work and optimize the schedule whilst minimizing the cost of the process. In this aspect, there are some points that must always be considered in the adopted strategy.

Once the organizational structure of laboratories/units has been set, as discussed in Section 2.1, the next step is to build a time chart highlighting the requirements of ISO/IEC 17025 standard which will also account for any existing internal requirements specifically applied to the provided testing services. Additionally, this time frame should specify the responsibilities of the laboratory staff members in order to organize the process. For improving the results, production and registration of technical documents related to quality assurance of testing results should be considered as the critical steps of the process. Such documents are technical standards for equipment operation, calibration and maintenance, standards for testing execution and forms used to record testing results and also any procedure related to quality assurance. Indeed, this type of implementation project management was discussed by Silva et al. [7] and, in brief, should be designed considering the following points:

http://dx.doi.org/10.5772/66100

- Clear scope definition: scope definition influences all the chronogram steps. It is crucial to clearly select the testing services that will be covered by the quality management system, and, if the laboratory is part of a large company or institute, to identify the quality management documents that dispose about laboratory activities. This item may be considered pretty basic and obvious, but these observations are essential to speed up the process;

- Connections between different requirements of ISO/IEC 17025 and other pertinent documents: the chronogram should carefully consider the connections between the different requirements of ISO/IEC 17025 and also between these requirements and other requisites from internal documents or even other standards. The understanding of the connections is important in order to avoid the superposition of tasks. It also prevents proposition of simultaneous tasks that would result better if executed in sequence;

- Impact of system implementation on on-going activities: as briefly mentioned before, it is important to consider that a quality management system is often implemented in a laboratory where some processes are already in place. When this is the case, it is crucial to minimize the impact of task implementation concerning the on-going processes. This point is especially relevant in laboratories where researchers are also responsible for the quality system management;

- Attribution of tasks: the clear designation of the staff members responsible for carrying-out each step of the project management schedule is important not only due to the practical execution of the tasks, but also to optimize the process follow-up. It also improves the communication within the team responsible for implementing the system and, consequently, the compromise between different processes that may be related; and

- Follow-up program: it is important for the chronogram to specify the follow-up strategy. The appropriate strategy depends on the case and it may work with periodic check-up of the on-going activities or with continuous monitoring.

From those points, the definition of a suitable follow-up strategy is of paramount importance for optimizing the quality system management implementation process, because it enables 'on-the-fly' changes of the adopted strategy and timeframe. When the latter is organized on the basis of requirements and all the tasks are clearly assigned, it is possible to develop a simple and efficient follow-up programme. It is easier to know how many people are assigned to specific tasks and to verify the relative progress of different tasks. This information is essential to quickly adjust chronograms and even the strategy when necessary.

A functional follow-up programme is an effective tool for checking the system's maturity determining when it is time to perform a deeper analysis in order to identify fails or gaps in the implementation process. One of the most useful tools to perform this sort of analysis is an internal auditing, which results in an improved diagnostic when compared to the previous follow-up system. This detailed diagnostic is fundamental to carry out the last adjustments necessary to finish the system implementation. The main steps of the implementation project discussed above and its relationships are shown in **Figure 2**.

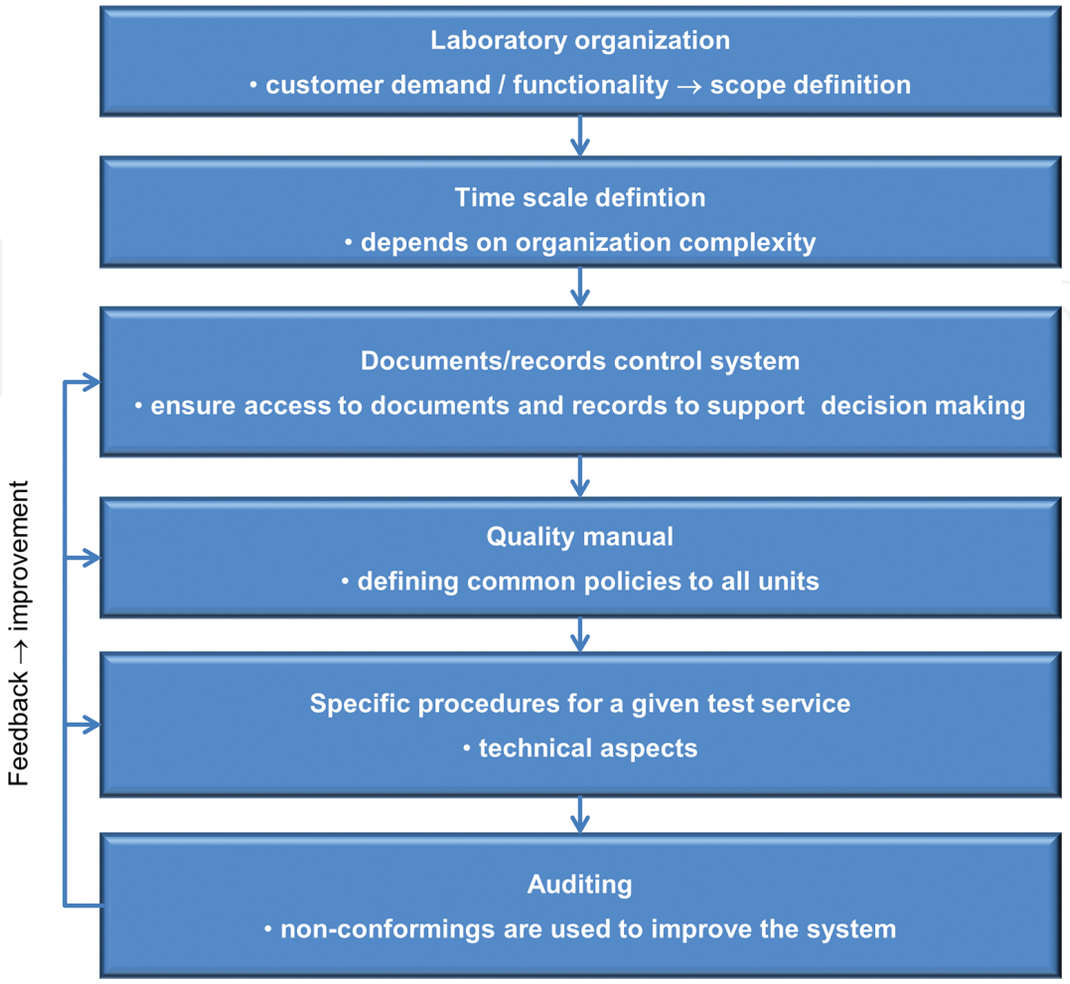

Figure 2. Main steps of a quality management system implementation project.

A last important practical aspect to be mentioned is the financial impact of implementing a quality management system at a laboratory. A deployed quality management system standardizes the processes of the laboratory, demonstrating measurement capability and technical competence. All these aspects add credibility to the results and demonstrate laboratory commitment to the customer. As a consequence, those aspects also translate into financial success by productivity increase, reduced rework and a smaller number of errors. Additionally, standardization of the supplier evaluation process, pricing policy, and careful selection of subcontracts also decreases financial costs. On the other hand, the requirements of a quality system according to ISO/IEC 17025, such as audits, calibrations, and inter-comparisons bring additional costs to the laboratory. In this aspect, Barradas and Sampaio [29], had shown that investments are feasible and customer satisfaction is improved.

3.2. Implementation time scale

The time necessary for implementing a quality management system depends basically on the size and complexity of the company/laboratory. It scales with the number of laboratories, testing services and R&D activities that the system will be applied. However, a functional

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approach to the organization of laboratories and services decreases the time consumed for system's implementation. Indeed, the latter may be regarded as the first step thereto.

For this reason, it is somehow difficult to estimate the time scale necessary for implementing the system without considering a specific case. However, if one considers that a typical structure is composed of a number of different laboratories under a common management centre (a R&D division or department, for example), it is possible to point out some strong time scale bottlenecks:

- Definition of general principles and documents common to all the laboratories: in large structures it consists in writing a 'manual of quality', with policies and processes common to all laboratories/units under the quality management system. Such document should standardize procedures and policies (mostly those related to management requisites—item 4 in ISO/IEC17025, as for instance, control of documents and records, non-conforming work management, and management assessment), but without hindering the work at the laboratories, ensuring flexibility necessary to deal with specific characteristics of different laboratories;
- System for documents and records control: implementation of an integrated system to provide fast access to documents, to control documents update and and to keep track and security of records at a large structure composed of several laboratories may be a very time-consuming task. Ideally, such a system should also include unified policies and electronic processes for back-up that increase the implementing time;
- Metrological traceability: as earlier mentioned, ensuring metrological traceability is not always a trivial task in materials characterization. For laboratories, implementing a quality management system 'from the scratch' it may implicate both minor aspects, like acquiring certified reference materials for calibration, and very time demanding actions, like training the staff and developing validate test procedures.

4. Final considerations

The implementation of a quality management system in materials science laboratories based on the ISO/IEC 17025 standard must fulfil the requirements outlined in the standard. However, due to the particular characteristics of the work realized in such laboratories, some requirements may be considered as key matters during the system implementation' these are as follows:

- Organization of the laboratories;
- Control of documents and records;
- Customer relationship service;
- Calibration and traceability to the international system of units;

- Quality assurance of results and
- Evaluation of uncertainty of measurement.

Some of these key matters should not only fulfil the standard requirements, but also provide the necessary flexibility for the activities carried out in those laboratories, especially those related to R&D management, like control of documents and records, for example. On the other hand, some of these topics are related to technical features specific for particular tests methods for materials characterization, such as evaluation of uncertainty and traceability. These last aspects may be considered independently of managerial aspects.

The success in implementing a functional and flexible quality management system in aforementioned science laboratories depends not only on the effective and efficient handling of these key factors, but also on the use of a suitable approach for implementing the system. This approach should use appropriate strategies and chronogram in order to facilitate the implementation follow-up and minimize the time and cost of the process.

One last, but not less important, consideration should be made on further improvement of quality assurance provided by materials science laboratories. As mentioned above in this chapter, materials science impacts innovation in several areas, both on the development of new materials and on the development and optimization of techniques for materials property characterization. In this context, it is very common that the use of new materials in commercial products give rise to safety concerns about the use of the product and its disposal in the environment [30, 31]. Some typical cases are, for example, the use of nanoparticles in cosmetics and pharmaceutical products [32], and use of new composites for engineering systems [33].

These issues are not directly related to the ISO/IEC 17025, but to specific international regulation for several products and to international standards used to perform materials and products tests. In this aspect, it is important for materials laboratories engaged in quality assurance to work proactively with national and international organizations responsible for standardization and/or regulation, collaborating on the development and optimization of standard procedures for materials characterization and proposition of technical criteria for utilization of materials for specific uses.

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